REMARKS

A. Status of the Specification, of the Claims, and the Amendment

These remarks are in response to the Office Action mailed August 25, 2005. Claims 5-48 were previously canceled. Claims 49-51 have been added. The amendment introduces no new matter. After the present amendment has been entered Claims 1-4 and 49-51 will be pending.

New claims 49-51 are similar to the original claims 1-3, but differ in that unlike claims 1-3, claims 49-51 do not recite homologues of Cdc25 or conservative variants of a polypeptide having an amino acid sequence SEQ ID NO:2

With respect to the specification, the Examiner requested that the specification be amended to reflect the relation of the present application to the U.S. Patent Application Serial Number 09/849,617 (see, item 2 on page 2 of the Office Action).

In response, the Applicants respectfully submit that this information has already been added by the preliminary amendment filed on July 11, 2003, simultaneously with the present application. The preliminary amendment specified that the present application is a divisional application of U.S. Serial Number 09/849,617 filed May 4, 2001, which is now issued as U.S. Patent No. 6,593,100. Accordingly, it is submitted that there is no need to amend the specification now.

B. Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-4 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (the enablement rejection) (see, item 5 on

page 2 of the Office Action). This rejection is respectfully traversed on the ground that the Examiner has not met the burden of demonstrating that the entire breadth and scope of the claims is allegedly not enabled.

The burden of demonstrating that the claims are not properly enabled is squarely on the Examiner, as required by *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). It is settled law that a presumption of enablement exists, and that ordinarily the lack of enablement rejection should not be given unless there are reasons to doubt the veracity of the statements in the application upon which the reliance for enablement is based. MPEP § 2164.04. It is respectfully submitted that in this case the Examiner has not met the burden of demonstrating the alleged lack of enablement.

The legal standard for determining the adequacy of enablement is well established. To be enabling, "the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Genentech Inc. v. NovoNordisk*, 108 F.3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997). The Applicants submit that the specification does comply with the enablement requirement.

More specifically, the Examiner has conceded that the claims are enabled for a purified polypeptide comprising SEQ ID NO:2. Clearly, the specification provides an example of determining of kinase activity towards Cdc25 (see, page 56, paragraphs [0175] and [0176]).

The Examiner, however, has stated that the amount of guidance provided in the specification is not sufficient to also enable the polypeptide capable of phosphorylating the homologues of Cdc25 as required by claim 1. The Examiner has further stated that the specification also fails to enable "conservative variants" of the polypeptide as required by claim 3. Finally, the Examiner has asserted that the specification also fails to

enable a polypeptide that is 80% homologous to the polypeptide comprising SEQ ID NO:2 as required by claim 4. The Examiner's opinion seems to be that large quantity of experimentation is required to practice the invention with respect to the homologues and conservative variants. The Applicants respectfully disagree.

The Applicants respectfully point out that it is only the necessity of undue experimentation that may make a specification non-enabling. Modest, reasonable quantity of experimentation is allowed, if it is routine or if the specification provides enough guidance. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). It has never been the rule that the specification itself must necessarily describe how to use every possible variant of the claimed invention. Indeed, "the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

Applying these principles to the facts of the present case, it is clear that since the specification provides enough guidance with respect to Cdc25, practicing the invention with respect to the homologues and conservative variants of Cdc25 would require no more than minor variations of what is described. Devising such minor variation are not more than common tasks routinely performed by competent researchers.

Indeed, in view of the definition of "homology" (see, page 10, paragraph [0042] of the specification), those having ordinary skill in the art would understand that the structure of the homologues of Cdc25 is very similar to that of Cdc25; accordingly, similar properties of Cdc25 and of the homologues are expected. Therefore, teaching how to practice the invention with respect to Cdc25 would also inherently teach how to practice the invention with respect to the homologues.

Also, in view of the definition of "conservative variants" (which includes replacement of an amino acid residue by another, biologically similar residue, as provided in paragraph [0039] on page 9 of the specification), those having ordinary skill in the art would understand that the biological properties of such conservatives variants of a polypeptide that comprises SEQ ID NO:2 would be very similar to the biological properties of the purified polypeptide itself. Therefore, teaching how to practice the invention with respect to the purified polypeptide would also inherently teach how to practice the invention with respect to its conservative variants.

It is well established that providing at least one method for making and using the invention is enough to satisfy the enablement requirement, so long as the example is reasonably correlated to the entire scope of the claim. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The examples provided in the specification teach how to practice the invention with respect to the purified polypeptide and with respect to Cdc25. Thus, the examples are reasonably correlated to the entire scope of the claims, which does include using the homologues and conservative variants in the manner described in the examples. Accordingly, under the *Fisher* standard, the enablement requirement has been met.

To summarize, it is respectfully submitted that the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, as allegedly lacking an enabling disclosure, is not properly applied. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

C. Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1, 3, and 4 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the

application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Just as in the situation with lack of enablement, the burden of demonstrating that the claims are allegedly not supported by an adequate written description is on the Examiner, as required by *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). MPEP specifically states that a strong presumption of adequacy of written description exists and directs that § 112, paragraph 1 rejections of an original claim should be rare. MPEP §§ 2163(I)(A) and 2163(II)(A). It is respectfully submitted that in this case the Examiner has not met this burden.

The legal standard for determining the adequacy of written description is clear and well established. The description is adequate if "the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at [the time of filing] of the later claimed subject matter." *Wang Labs Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767. In other words, the question of the lack of adequate written description does not arise unless "one skilled in the art [would not be able] to immediately envisage the product claimed..." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895. It is submitted that applying these broad principles to the present application, it can be unequivocally concluded that the written description in this application adequately supports the claims.

More particularly, the Examiner has conceded that the Applicants are in possession of a purified polypeptide comprising SEQ ID NO:2, but has asserted that they are not in possession of the homologues of Cdc25 or of the conservative variants of the polypeptide, and thus the specification allegedly contains insufficient written description to support the entire scope of the pending claims. The Applicants respectfully disagree.

The specification clearly discloses that the Applicants were, at the time the application was filed, in possession of both pure polypeptides having the sequence SEQ ID NO:2 and of conservative variants thereof (see, e.g., page 3, paragraph [0010]). The specification further discloses that the Applicants were, at the time the application was filed, in possession of polypeptides capable of phosphorylating both Cdc25 and homologues thereof (see, e.g., page 3, paragraph [0009]).

In view of the foregoing, the Applicants submit that the present specification contains a complete description of the invention sufficient to demonstrate that the Applicants, at the time the application was filed, had possession of the claimed invention. Accordingly, it is respectfully submitted that the rejection of claims 1, 3, and 4 under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description, is not properly applied. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

CONCLUSION

In view of the above remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fees is believed due in connection with this response. In the event that an additional fee is due, the Commissioner is hereby authorized to charge any amounts required by this filing, or credit any overpayment, to Deposit Account No. 07-1896.

Respectfully submitted,

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